



K964969

GE Medical Systems

General Electric Company  
P.O. Box 414 Milwaukee WI 53201

## Signa SP Crown Coils

December 10, 1996

JUN 26 1997

General Electric Medical Systems

### SUMMARY OF INFORMATION REGARDING SAFETY AND EFFECTIVENESS

This 510(k) summary of safety and effectiveness information is submitted in accordance with the requirements of 21 CFR Part 807.87(h).

Contact: Larry A. Kroger, Ph.D.  
Phone: 414-544-3894  
FAX: 414-544-3863

Product: Signa SP Crown Coils  
Manufactured by General Electric Medical Systems  
Waukesha, Wisconsin, USA

#### 1) Indications for Use

The Signa SP Crown Coil family provides imaging capability for the Signa SP MR System by facilitating magnetic resonance imaging of the head and extremities. These coils may also be used for dynamic (i.e., flexion of joints) magnetic resonance imaging of the extremities.

#### 2) Device Description

The Signa SP Crown Coils are a group of solenoidal transmit/receive surface coils of varying dimensions that are contained in a flexible, biocompatible outer covering.

#### 3) Marketing History

The Signa SP Crown Coils have not been previously marketed by GE Medical Systems.

#### 4) Potential Adverse Effects on Health

The use of the Signa SP Crown Coils does not result in any additional potential hazards compared to previously marketed flexible transmit/receive surface coils.

#### 5) Conclusions

It is the opinion of GE Medical Systems that the Signa SP Crown Coils are substantially equivalent with respect to materials and operation to the presently marketed transmit/receive flexible surface coil contained in the Signa SP MR System (K942604) and are similar in utility and general coil type (solenoid) to the 0.2T Extremity Coil (K954353).



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Larry Kroger, Ph.D.  
Manager, Safety and Regulatory Programs  
GE Medical Systems  
3200 North Grandview Blvd.  
Waukesha, WI 53188

Re: K964969  
Signa SP Crown Coils MRI Accessory  
Dated: April 3, 1997  
Received: April 4, 1997  
Regulatory Class: II  
21 CFR 892.1000/Procode: 90 MOS

JUN 26 1997

Dear Dr. Kroger:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4591 for Radiology devices, or 594-4613 for Ear, Nose and Throat devices. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,

Lillian Yin, Ph.D.  
Director, Division of Reproductive,  
Abdominal, Ear, Nose and Throat,  
and Radiological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

510(k) Number (if known):

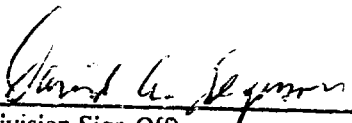
Device Name: Signa SP Crown Coils

Indications For Use:

The Signa SP Crown Coil family provides imaging capability for the Signa SP MR System by facilitating magnetic resonance imaging of the head and extremities and providing a mechanism for dynamic (i.e., flexion of joints) magnetic resonance imaging of the extremities.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

  
\_\_\_\_\_  
(Division Sign-Off)

Division of Reproductive, Abdominal, ENT,  
and Radiological Devices

510(k) Number K964969

Prescription Use X  
(Per 21 CFR 801.109)

OR

Over-The-Counter Use \_\_\_\_\_